Prazosin for the treatment of Obsessive Compulsive Disorder: An open label, fixed dose add-on study.

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To determine whether the addition of the *1 adrenoreceptor antagonist prazosin to SSRI is useful for patients with OCD who do not respond to SRI monotherapy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON32256

Source
ToetsingOnline

Brief title
Prazosin for therapy resistant OCD.

Condition

- Psychiatric disorders

Synonym
obsessive compulsive disorder/ compulsion

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dopamin, OCD, prazosin

Outcome measures

Primary outcome

Change in Yale Brown obsessive-compulsive scale (Y-BOCS) and the number of responders (at least 25% change on the Y-BOCS and final CGI rating of *much improved* or *very much improved for two consecutive times).

Secondary outcome

Changes on following rating scales:

CGI: clinical global impression scale

BABS: Brown assessment of beliefs scale

HDRS: Hamilton depression rating scale

HAS: Hamilton anxiety rating scale

PADUA INVENTORY: measuring the degree of distress causes by OC symptoms

SPQ: measuring the degree of schizotypic personality

SEEHAN DISABILITY SCALES (SDS): measures functional impairment in three domains (social, family and work)

Study description

Background summary

The neurotransmitter serotonin has been implicated in the pathophysiology of OCD. However, 40% to 60% of the patients remain unimproved after treatment with serotonin re uptake inhibitors (SRIs).
Prazosin is a central nervous system active *1 adrenoreceptor antagonist and

has been registered as an anti-hypertensive agent.
Given the (1) involvement of the dopaminergic system in OCD, (2) in vitro findings of dopaminergic neuro-modulation by prazosin in limbic-striatal and cortical structures, and (3) the efficacy of prazosin in anxiety disorders (PTSD), we hypothesize a beneficial effect of prazosin addition to SRIs in OCD patients.

Study objective

To determine whether the addition of the *1 adrenoreceptor antagonist prazosin to SSRI is useful for patients with OCD who do not respond to SRI monotherapy.

Study design

The trial will have an open-label design with a fixed dose regimen, with prazosin being added to ongoing SRI treatment.

Intervention

Prazosin will be administered at the maximum tolerable dosage in addition to an SRI for 12 weeks.

Study burden and risks

There are no serious risks associated with this study, aside from transient side-effects. Immediate advantage can be expected because of the potential therapeutic effect in this severe and therapie-resistent type of OCD. Also, the results can offer insight into the pathophysiology of OCD and may lead to future development of more effective medication.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

DSM IV diagnosis obsessive-compulsive disorder
Y-BOCS score > 16
Therapy resistance (no response to at least 1 previous SRI treatment)
Male and female, aged 18-70 years
negative pregnancy test
Written informed consent

Exclusion criteria

Presence of major depression (HDRS>15), bipolar disorder, schizophrenia or any other psychotic condition, tic disorder, substance related disorder during the past 6 months, epilepsy, or any structural CNS disorder or stroke within the last year.
Evidence of clinically significant and unstable somatic abnormalities.
Patients at risk for suicide
Multiple serious drug allergies or known allergy for the trial compounds
Use of antipsychotics during 6 months before the screening visit
Use of any other psychotropic drug during 6 months before the screening visit
Cognitive and behavioural treatment 3 months prior to the screening visit
Use of drugs that interact with prazosin: diuretic, other antihypertensive agents, regular use of alcohol.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	prazosin
Generic name:	Prazosin hydrochloride
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2008-001017-14-NL
CCMO	NL21739.018.08